REMARKS

The Office Action dated August 8, 2007, has been reviewed, and the comments of the U.S. Patent Office have been considered.

Claims 93 and 94 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. This rejection is applied, without distinction, to Claims 132 – 134, even though these claims are limited to a specific peptide, or a specific binding site. The rejection of all claims is respectfully traversed.

Initially, Applicants express their appreciation for withdrawal of the rejection over prior art, and share the Examiner's conviction that the pending claims are directed to subject matter undisclosed by those who came before them. It is against this backdrop that Applicant's claims, directed to methods of inhibiting what is one of the recognized scourges of modern mankind, HIV, that the claims must be considered. The Examiner rejects these claims because, although the application demonstrates that the core of the invention, inhibiting binding between TSG101 and the HIV Gag polypeptide, is demonstrated by *in vitro* example, the Examiner asserts, outstanding Office Action, page 5, that no correlation has been shown between inhibition of TSG101 binding and HIV inhibition, *in vivo*.

While it is respectfully submitted that demonstration of *in vivo* results is not the standard of the law, *In re Brana,* 34 USPQ2d 1436 (Fed. Cir. 1995), Applicants submit herewith the entire disclosure of U.S. Patent Application Serial Number 11/940,714, filed November 15, 2007. Reliance on data and results set forth in another patent application is proper in response to a rejection for lack of enablement. *Ex parte Ebata,* 19 USPQ2d 1952 (BPAI 1991). Attention is respectfully directed to Examples 2 and 3 thereof, p. 65 – 72, directed to the effect of specifically

inhibiting binding between those aspects of TSG101 and HIV recited in the claims. As is shown therein, and in the accompanying figures, inhibition or blocking of binding between HIV and TSG101, as shown in the pending application , is effective in inhibiting HIV as a means of treatment. Accordingly, the link between the demonstrated *in vitro* results of the above-captioned application and *in vivo* effectiveness having been shown by data, withdrawal of the rejection for lack of enablement is respectfully requested. (In this respect, Applicants note that the submission of this data is specifically invited by the observation, in the outstanding action, that a representative class of agents recited is antibodies – see page 3.)

Beyond Applicants' showing herein, Applicants respectfully submit that the Examiner's rejection inverts the burden of proof. Applicants have laid a carefully constructed and logical explanation of the method of interaction between the agent of the claims and the infective path of HIV. They have shown the critical effect, that inhibiting binding inhibits particle generation. All of this the Examiner accepts. Yet, the Examiner rejects the proposition that without HIV particle generation, HIV infectivity will be limited, because "the prior art teaches against the correlation between *in vitro* success and *in vivo* drug efficacy." Yet, the Examiner acknowledges that these prior art issues, including viral drug-resistance, oral bioavailability, short half-life, etc., (Action, page 4 and again, page 5) are features of an agent *targeted against the virus* not at interfering with interaction between a host protein (TSG101) and the virus. By shifting emphasis to the host protein, the prior art obstacles observed are overcome. Thus, there is no reasonable basis advanced for doubting the scientific explanation and date in the case as originally filed.

Further, Applicants note that contrary to the characterization in the Office Action, page 3, the claims rejected are not all of the same scope. Claim 132, for example, does not recite "a genus of unspecified compounds that bind TSG101 proteins" but rather a very specific agent, a

single sequence. Again, it is respectfully submitted that working up the appropriate assays and protocols for ONE sequence would not present a challenge to one of skill in this art that would require the application of inventive skill – Applicants' claims do not call for curing HIV, they call for treatment through inhibition of particle generation – the same has been demonstrated.

Finally, Applicants note that the prohibition on experimentation is ***undue experimentation.*** Non-inventive work, a lot of it, is routine in any development of an anti-viral therapy. The same is true here. Identification of preferred forms, and optimum protocols, given the teaching herein, is not beyond the level of skill in the art, a *Wands* factor not considered in the outstanding Office Action, but nonetheless a component of the law on enablement. Respectfully, applicants submit that to meet the standard of the law, which, *imprimus*, imposes the burden of proof on the Examiner to demonstrate why Applicant's claims are unreasonable, all that needs be done is to provide a basis which allows success in routine investigation. The "roadblocks" to efficacious treatment identified as part of the prior art are simply not applicable to the claimed invention. The rejection is respectfully traversed.

CONCLUSION

In view of the foregoing data and remarks, Applicants respectfully request withdrawal of the single outstanding rejection, reconsideration of this Application and the prompt allowance of at least claims 93, 94 and 132-134.

Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact the undersigned to expedite prosecution of the application.

The Commissioner is hereby authorized by this paper to charge any fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 10-0233.

Respectfully submitted,

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